

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

NATIONAL PHASE PCT

Atty. Docket: KAMEI=2

In re Application of: ) Conf. No.: 4282  
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**Kenshi KAMEI et al** ) Art Unit: 1614  
                       ) )  
I.A. Filing Date: 10/24/2003 ) Examiner: P. G. SPIVACK  
371(c) Date: 04/25/2005 ) )  
                       ) Washington, D.C.  
U.S. Appln. No.: 10/532,585 ) )  
                       ) )  
For: THERAPUTIC AND/OR ) April 8, 2009  
PREVENTIVE AGENT... ) )

**SECOND REPLY TO FINAL ACTION: DECLARATION OF EARLIER INVENTION**

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building, Mail Stop Amendments  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Replying further to the Final rejection of October 8, 2008, applicants file herewith an RCE, a petition for three (3) months' extension of time, and a Declaration under 37 CFR 1.131 (with attachments).

In the Final rejection, all the claims are rejected as obvious under Section 103 from the Koga et al publication, on the basis that Koga et al is prior art under 35 USC 102(a). The Koga et al publication, bearing a copyright date of 2002, has four authors, two of whom are with the Assignee of the present application, and it discloses data relating to the pharmacology of GM-611, the compound of the present invention, such data in large part being based on the present invention.

To prove that this is so, i.e. that the present invention was completed prior to the publication date of Koga et al., attached hereto is a Declaration under 37 CFR 1.131 in the name of one of the present applicants/inventors, namely Hideki Sato. Attached to the Declaration and made part thereof is redacted copy<sup>1</sup> of relevant part of a "Clinical Study Report" in Japanese (with English translation) dated well in advance of the date of Koga et al (earliest possible publication date: March, 2002). The Declaration and attached Clinical Study Report establish completion of the present invention prior to the publication date of the Koga et al publication.

In view of the attached Declaration, the Koga et al publication is not "prior art", and the rejection must be withdrawn.

Applicants respectfully request favorable consideration and early formal allowance.

Respectfully submitted,

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By



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<sup>1</sup> The parts of the Clinical Study Report and English translation which are blacked out are not relevant or material to the evidence presented, and are not necessary under the provisions of 37 CFR 1.131.